December 9, 2021

Corentec Co., Ltd.
Sungwon Yang
QMR
12, Yeongsanhong 1-gil, Ipjang-Myeon, Seobuk Gu
Cheonan-si, Chungchongnam-do 31056
SOUTH KOREA

Re: K212034
Trade/Device Name: LOSPA TKR System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH
Dated: November 3, 2021
Received: November 3, 2021

Dear Sungwon Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ting Song -S

Ting Song, Ph.D., R.A.C.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212034

Device Name
LOSPA TKR System

Indications for Use *(Describe)*

LOSPA TKR System is intended for use in total knee arthroplasty surgery for the following indications:

• Painful, disabling joint disease of the knee resulting from non-inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis;
• Post-traumatic loss of knee joint configuration and function;
• Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
• Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous arthroplasty procedure.

LOSPA TRK System is intended for cemented application only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

Corentec Co.,Ltd.
LOSPA TKR System
- Specification Inclusion
of its instrumentation
June 23th, 2021

ADMINISTRATIVE INFORMATION

Manufacturer: Corentec Co., Ltd.
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	LOSPA TKR System
Common Name:	Total Knee Joint Replacement Prosthesis
Classification Regulations:	21 CFR 888.3560
Class:	II
Product Codes:	JWH, MBH
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

INTENDED USE

The intended use of the added specification has not changed as a result of the modification of the predicate device cleared under LOSPA Total Knee System, K110404 & K130673 & K160157 & K192507 & K200395.

The LOSPA Total Knee Replacement System is intended for use in total knee arthroplasty surgery for the following indications:

- Painful, disabling joint disease of the knee resulting from non-inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis;
- Post-traumatic loss of knee joint configuration and function;
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
- Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous arthroplasty procedure.

The LOSPA Total Knee Replacement System is intended for cemented use only.

DEVICE DESCRIPTION

The Additional components being added to the LOSPA TKR System are:
- Instrumentation (Tibial Insert Trial)

The subject LOSPA TKR System components specification inclusions are a line extension of Instrumentation (Tibial Insert trial). The following is the additional components.

A) Instrumentation (Tibial Insert Trial)

A copy of a final tibial prosthesis designed to be used during total knee arthroplasty to determine the correct alignment, size, and fit of the final prosthesis. It is one of a set of trial knee prostheses that match the different anatomical structures of the knee joint, and may be used in conjunction with a knee femoral component trial prosthesis and a tibial baseplate trial prosthesis. This instrument is a reusable device that must be sterilized prior to use.

Additional Tibial Insert Trials are designed based on Tibial Insert Trials of predicate device cleared LOSPA TKR System Instrumentation under K110404 & K130673 & K160157 & K192507 & K200395. There is one eliminated size, 26T of each design (CR and PS), each for left and right sides. For both CR and PS designs, the ranges of dimensions are the same. The components have slightly modified height. Except for the differences of height, lengths are identical to the previously cleared Tibial insert trials. The subject LOSPA TKR System is available in nine proportional sizes.

This Tibial Insert Trials are made of Propylux conforming to ASTM D4101: Standard Classification System and Basic for Specification for Polypropylene Injection and Extrusion Materials.

SUBSTANTIAL EQUIVALENCE

LOSPA TKR System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

Substantially equivalent products for LOSPA TKR System are as follows,